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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Santoro et al.

Serial No.: 09/533,399

Group Art Unit: 1614

Filed: March 22, 2000

Examiner: To be assigned

For: METHODS OF TREATING
INFLAMMATORY AND VIRAL
DISORDERS BY ADMINISTERING
CYCLOPENTENONE COMPOUNDS

Attorney Docket No.: 10167-004

**INFORMATION DISCLOSURE STATEMENT UNDER
37 C.F.R. § 1.56 and § 1.97**

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

In accordance with the continuing duty of disclosure imposed by 37 CFR § 1.56 to inform the Patent and Trademark Office of all references coming to the attention of each individual associated with the filing or prosecution of the subject application, which are or may be material to the patentability of any claim of the application, Attorneys for Applicants hereby direct the Examiner's attention to the references AA to CR listed on the attached revised form PTO 1449. Copies of references AD-CR are enclosed herewith. References AA-AC are the U.S. national stage applications corresponding to the PCT publications of references AE-AG and are listed for the Examiner's convenience.

Identification of the listed references is not to be construed as an admission of Applicants or Attorneys for Applicants that such references are available as "prior art" against the subject application. Consequently, Applicants respectfully decline to use form PTO-

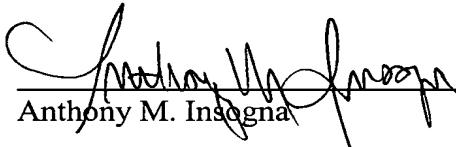
1449, since this form identifies all of the references cited therein as "Prior Art." As an alternative, Applicants submit herewith a "revised form PTO 1449" entitled "List of References Cited" instead of "List of Prior Art Cited."

Applicants respectfully request that the Examiner review the foregoing references and that the references be made of record in the file history of the application.

Pursuant to 37 CFR § 1.97(b), since this Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits, it is submitted that no fee is due in connection herewith. However, should the Patent and Trademark Office determine otherwise, please charge the required fee to Pennie & Edmonds LLP Deposit Account No. 16-1150.

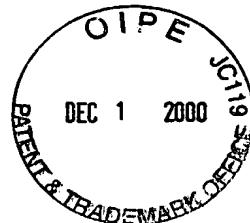
Respectfully submitted,

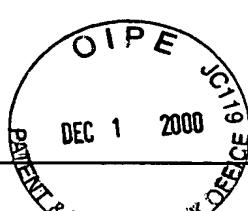
Date: December 1, 2000



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LIST OF REFERENCES CITED BY APPLICANT <i>(Use several sheets if necessary)</i>		ATTY. DOCKET NO.	APPLICATION NO.
		10167-004	09/533,399
		APPLICANT	
		Santoro et al.	
FILING DATE		GROUP	
March 22, 2000		1614	

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
AA	09/202,553		Amici et al			12/16/98
AB	09/319,743		Santoro et al			6/10/99
AC	09/446,731		Santoro et al.			12/23/99
AD	4,954,519	9/4/90	Powers et al.			
CR	6,111,145	8/29/00	Kobayashi et al			

FOREIGN PATENT DOCUMENTS

	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO
AE	WO 97/48389	12/24/97	PCT (prio doc)				
AF	WO 98/25593	6/18/98	PCT (prio doc.)				
AG	WO 99/01117	1/14/99	PCT (prio doc)				
AH	DE 4311835	10/13/94	Germany				X
CM	EP 0 131 441	1/16/85	EPO				
CN	JP 60-97926	5/31/85	Japan				X
CO	JP 61-47437	3/7/86	Japan				X
CP	JP 63-72672	4/2/88	Japan				X
CQ	WO 98/41196	9/24/98	PCT				X

OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

AI	Centers for Disease Control and Prevention, 1996, "Prevention and Control of Influenza: Recommendations of the Advisory Committee on Immunization Practices", <i>Morbid. Mortal. Weekly Rep.</i> 45(RR-5):1-24
AJ	Amici et al., 1995, "Aspirin Enhances Thermotolerance in Human Erythroleukemic Cells: An Effect Associated with the Modulation of the Heat Shock Response", <i>Cancer Res.</i> 55:4452-4457
AK	Amici et al., 1994, "Selective Inhibition of Virus Protein Synthesis by Prostaglandin A ₁ : a Translational Block Associated with HSP70 Synthesis", <i>J. Virol.</i> 68:6890-6899
AL	Amici et al., 1993, "Induction of Thermotolerance by Prostaglandin A in Human Cells", <i>Exp. Cell Res.</i> 207:230-234
AM	Amici et al., 1992, "Antiproliferative Prostaglandins Activate Heat Shock Transcription Factor", <i>Proc. Natl. Acad. Sci. USA</i> 89:6227-6231
AN	Baeuerle and Henkel, 1994, "Function and Activation of NF- κ B in the Immune System", <i>Annu. Rev. Immunol.</i> 12:141-179
AO	Baldwin, 1996, "The NF- κ B and I κ B Proteins: New Discoveries and Insights", <i>Annu. Rev. Immunol.</i> 14:649-681



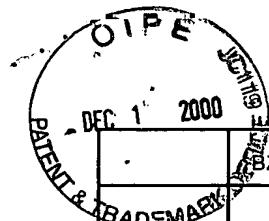
		Becker et al., 1995, "Analysis of Proteins that Interact with the IL-2 Regulatory Region in Patients with Rheumatic Diseases", <i>Clin. Exp. Immunol.</i> <u>99</u> :325-330
	AQ	Breithaupt et al., 1996, "The Suppression of T Cell Function and NF κ B Expression by Serine Protease Inhibitors Is Blocked by N-Acetylcysteine", <i>Cell. Immunol.</i> <u>173</u> :124-130
	AR	Chen et al., 1995, "Dependence and Reversal of Nitric Oxide Production on NF- κ B in Silica and Lipopolysaccharide-Induced Macrophages", <i>Biochem. Biophys. Res. Comm.</i> <u>214</u> :839-846
	AS	Conant et al., 1996, "Extracellular Human Immunodeficiency Virus Type 1 Tat Protein Is Associated with an Increase in both NF- κ B Binding and Protein Kinase C Activity in Primary Human Astrocytes", <i>J. Virol.</i> <u>70</u> :1384-1389
	AT	Conti et al., 1999, "Antiviral Effect of Hyperthermic Treatment in Rhinovirus Infection", <i>Antimicrob. Agents Chemother.</i> <u>43</u> :822-829
	AU	Denko et al., 1997, "Protease Inhibitor TPCK Represses Ha-ras (Val12) Transformation and Nuclear Factor κ B Activation", <i>Int. J. Oncol.</i> <u>10</u> :895-900
	AV	Elia et al., 1999, "Induction of Ferritin and Heat Shock Proteins by Prostaglandin A ₁ in Human Monocytes. Evidence for Transcriptional and Post-Transcriptional Regulation" <u>264</u> :736-745
	AW	Feige and van Eden, 1996, "Infection, Autoimmunity and Autoimmune Disease", in: <u>Stress-Inducible Cellular Responses</u> , Feige et al, eds., Birkhäuser Verlag, Basel, pp. 359-373
	AX	Finco et al., 1994, "Inducible Phosphorylation of I κ B α Is Not Sufficient for Its Dissociation from NF- κ B and Is Inhibited by Protease Inhibitors", <i>Proc. Natl. Acad. Sci USA</i> <u>91</u> :11884-11888
	AY	Fukushima et al., 1982, "9-Deoxy- Δ^9 -Prostaglandin D ₂ , a Prostaglandin D ₂ Derivative with Potent Antineoplastic and Weak Smooth Muscle-Contracting Activities", <i>Biochem. Biophys. Res. Comm.</i> <u>109</u> :626-633
	AZ	Grimm and Baeuerle, 1993, "The Inducible Transcription Factor NF- κ B: Structure-Function Relationship of Its Protein Subunits", <i>Biochem. J.</i> <u>290</u> :297-308
	BA	Guesdon et al., 1995, "Interleukin 1-Induced Phosphorylation of MAD3, the Major Inhibitor of Nuclear Factor κ B of HeLa Cells. Interference in Signalling by the Proteinase Inhibitors 2,4-Dichloroisocoumarin and Tosylphenylalanyl Chloromethylketone", <i>Biochem. J.</i> <u>307</u> :287-295
	BB	Halazy et al., 1992, "Synthesis and Antiviral Properties of New Cycloalkanol Derivatives of Guanine", <i>Nucleosides & Nucleotides</i> <u>11</u> :1595-1606
	BC	Hungate et al., 1991, "Synthesis of Cyclic Valine Analogs", <i>Tetrahed. Lett.</i> <u>32</u> :6851-6854
	BD	Lee et al., 1978, "Antitumor Agents. 32. Synthesis and Antitumor Activity of Cyclopentenone Derivatives Related to Helenalin", <i>J. Med. Chem.</i> <u>21</u> :819-822
	BE	Lenardo and Baltimore, 1989, "NF- κ B: A Pleiotropic Mediator of Inducible and Tissue-Specific Gene Control", <i>Cell</i> <u>58</u> :227-229
	BF	Lindquist et al., 1988, "The Heat-Shock Proteins", <i>Annu. Rev. Genet.</i> <u>22</u> :631-677
	BG	Liu et al., 1996, "Attenuated Heat Shock Transcriptional Response in Aging: Molecular Mechanism and Implication in the Biology of Aging", in: <u>Stress-Inducible Cellular Responses</u> , Feige et al., eds., Birkhäuser Verlag, Basel, pp. 393-408

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PATENT & TRADEMARK OFFICE	BH	Marber et al., 1994, "Myocardial Protection after Whole Body Heat Stress in the Rabbit Is Dependent on Metabolic Substrate and Is Related to the Amount of the Inducible 70kD Heat Stress Protein", <i>J. Clin. Invest.</i> <u>93</u> :1087-1094
	BI	María et al., 1995, "Gastric Cytoprotective Activity of 2-Cyclopenten-1-one and Related Compounds", <i>Biol. Pharm. Bull.</i> <u>18</u> :1784-1786
	BJ	Morimoto and Santoro, 1998, "Stress-Inducible Responses and Heat Shock Proteins: New Pharmacologic Targets for Cytoprotection", <i>Nature Biotechnol.</i> <u>16</u> :833-838
	BK	Morimoto et al., 1992, "Transcriptional Regulation of Heat Shock Genes. A Paradigm for Inducible Genomic Responses", <i>J. Biol. Chem.</i> <u>267</u> :21987-21990
	BL	Nakagawa et al., 1982, "Effect of Proteinase Inhibitors Having Anti-Inflammatory Activity on Gelatinase, Elastase and Cathepsin G Isolated from Rat Polymorphonuclear Leukocytes", <i>J. Pharm. Dyn.</i> <u>5</u> :319-327
	BM	Parker et al., 1995, "Antiviral Effect of Cyclopentenone Prostaglandins on Vesicular Stomatitis Virus Replication", <i>Antiviral Res.</i> <u>26</u> :83-96
	BN	Pica et al., 1996, "Effect of Combined α IFN and Prostaglandin A ₁ Treatment on Vesicular Stomatitis Virus Replication and Heat Shock Protein Synthesis in Epithelial Cells", <i>Antiviral Res.</i> <u>29</u> :187-198
	BO	Pica et al., 1993, "Inhibition of Vesicular Stomatitis Virus Replication by Δ^{12} -Prostaglandin J ₂ is Regulated at Two Separate Levels and Is Associated with Induction of Stress Protein Synthesis", <i>Antiviral Res.</i> <u>20</u> :193-208
	BP	Polia and Cossarizza, 1996, "Stress Proteins in Inflammation", in: <i>Stress-Inducible Cellular Responses</i> , Feige et al., eds., Birkhäuser Verlag, Basel, pp. 375-391
	BQ	Rossi et al., 2000, "Anti-Inflammatory Cyclopentenone Prostaglandins are Direct Inhibitors of I κ B Kinase", <i>Nature</i> <u>403</u> :103-108
	BR	Rossi et al., 1997, "Inhibition of Nuclear Factor κ B by Prostaglandin A ₁ : An Effect Associated with Heat Shock Transcription Factor Activation", <i>Proc. Natl. Acad. Sci. USA</i> <u>94</u> :746-750
	BS	Rossi et al., 1996, "HSF Induction by Cyclopentenone Prostaglandins Prevents NF- κ B Activation in Human Cells: Implications in the Control of Virus Infection", Meeting on Molecular Chaperones and the Heat Shock Response, May 1-May 6, 1996, p. 255
	BT	Rossi et al., 1996, "2-Cyclopenten-1-one, a New Inducer of Heat Shock Protein 70 with Antiviral Activity", <i>J. Biol. Chem.</i> <u>271</u> :32192-32196
	BU	Rossi et al., 1995, "Induction by Prostaglandin A ₁ of Haem Oxygenase in Myoblastic Cells: an Effect Independent of Expression of the 70 kDa Heat Shock Protein", <i>Biochem. J.</i> <u>308</u> :455-463
	BV	Rozera et al., 1996, "Inhibition of HIV-1 Replication by Cyclopentenone Prostaglandins in Acutely Affected Human Cells", <i>J. Clin. Invest.</i> <u>97</u> :1795-1803
	BW	Salminen et al., 1995, "Alteration of Transcription Factor Binding in the Ischemic Rat Brain", <i>Biochem. Biophys. Res. Comm.</i> <u>212</u> :939-944
	BX	Santoro, 2000, "Heat Shock Factors and the Control of the Stress Response", <i>Biochem. Pharmacol.</i> <u>59</u> :55-63
	BY	Santoro and Roberts, 1999, "Search for Novel Cytoprotective and Antiviral Prostanoids", <i>Drug News Perspect</i> <u>12</u> :395-400



	FBZ	Santoro, 1997, "Antiviral Activity of Cyclopentenone Prostanoids", Trends Microbiol. <u>5</u> :276-281
	CA	Santoro, 1996, "Viral Infection", in: <u>Stress-Inducible Cellular Responses</u> , Feige et al., eds., Birkhäuser Verlag, Basel, pp. 337-357
	CB	Santoro, 1994, "Heat Shock Proteins and Virus Replication: HSP70s as Mediators of the Antiviral Effects of Prostaglandins", Experientia <u>50</u> :1039-1047
	CC	Santoro et al., 1990, "Induction of HSP70 by Prostaglandins", Chapter 3 in <u>Stress Proteins</u> , Schlessinger et al., eds., Springer-Verlag, Berlin, pp. 27-44
	CD	Santoro et al., 1989, "Prostaglandins with Antiproliferative Activity Induce the Synthesis of a Heat Shock Protein in Human Cells", Proc. Natl. Acad. Sci. USA <u>86</u> :8407-8411
	CE	Santoro et al., 1988, "Antiviral Activity of a Synthetic Analog of Prostaglandin A in Mice Infected with Influenza A Virus", Arch. Virol. <u>99</u> :89-100
	CF	Schnebli, 1974, "Growth Inhibition of Tumor Cells by Protease Inhibitors: Consideration of the Mechanisms Involved", Cold Spring Harbor Conferences on Cell Proliferation, Vol. 1, Control of Proliferation in Animal Cells Clarkson et al., eds., Cold Spring Harbor Laboratory Press, CSH, NY
	CG	Superti et al., 1998, "Inhibition of Rotavirus Replication by Prostaglandin A: Evidence for a Block of Virus Maturation", J. Infect. Dis. <u>178</u> :564-568
	CH	Thanos and Maniatis, 1995, "NF-κB: A Lesson in Family Values", Cell <u>80</u> :529-532
	CI	Wu et al., 1996, "Inhibition of NF-κB/Rel Induces Apoptosis of Murine B Cells", EMBO J. <u>15</u> :4682-4690
	CJ	Yang and Schnellmann, 1996, "Proteinases in Renal Cell Death", J. Toxicol. Environ. Health <u>48</u> :319-332
	CK	Zabel et al., 1991, "DNA Binding of Purified Transcription Factor NF-κB", J. Biol. Chem. <u>266</u> :252-260
	CL	Zhirnov et al., 1986, "Alphavirus Replication in Cultured Cells and Infected Animals Is Inhibited by Antiproteinase Agents", Antiviral Res. <u>6</u> :255-265

EXAMINER

DATE CONSIDERED

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.